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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0257; Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

Devro Inc. welcomes the opportunity to comment on the recordkeeping requirements proposed in conjunction with the Food and Drug Administration's (FDA's) efforts to protect the US food supply from any potential risks posed by bovine spongiform encephalopathy (BSE). 69 Fed. Reg. 42275 (July 14, 2004).

Devro Inc. is the largest domestic producer of collagen sausage casing in the US. Our South Carolina based operation employs over 350 people exclusively in the manufacture of collagen casings. From this site, we supply a wide variety of US and export customers but with the great majority of our production being sold in the US. Devro Ltd., our UK based parent company, is the world's leading producer of collagen sausage casings with several manufacturing locations in Europe and Asia.

While the details of the processes employed at our various locations are slightly different, in all cases we use the same basic raw material, bovine skin collagen. In the case of our US operations, this skin collagen is obtained as a by-product of the leather industry. Our partner leather tanneries obtain all their hides from USDA inspected slaughterhouses.

Devro strongly supports FDA's efforts to eliminate any potential risk to the US food supply from BSE. However, we believe that our product, collagen casings, poses unique issues that may not have been taken into account by FDA in drafting the proposed rule and the related interim final rule banning "prohibited cattle materials" from human food and cosmetics. We urge FDA to address these issues clearly in its final rulemaking. With regard to the proposed rule, we urge FDA to permit collagen casing manufacturers to satisfy the recordkeeping requirement by maintaining a continuing guarantee from their collagen suppliers affirming that all of the collagen they supply comes from the hides of cattle slaughtered at federally inspected establishments.

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1. Background Information

Collagen casings are made exclusively from collagen obtained from hides and skins.[1] No other cattle materials are involved in the manufacture or processing of collagen casings. At the present time, there are only two companies manufacturing collagen casing in the United States.

The process begins with removal of the cattle hide at a federally inspected establishment. All of the collagen used by Devro to make collagen casings comes from the hides of cattle slaughtered at federally inspected establishments. Almost immediately after slaughter, the hide is removed from the animal and separated from the rest of the carcass. The hide is immediately immersed in cold water that cools the hide to maintain leather quality. Removal of the hide occurs before removal of the head, brain, vertebral column, spinal cord, and other specified risk materials (SRMs). Therefore, the hide does not come into contact with, and cannot be contaminated by SRMs.[2]

The hide is then shipped to a tannery where it is washed to remove any loose material. Next, the hide undergoes hair removal and fleshing (removal of any remaining meat or fat). The hide is then split longitudinally to separate the outer layer for use in leather production from the interior collagen layer. The collagen layer then goes into equipment dedicated to food grade collagen where some additional preliminary processing occurs before being shipped to Devro's plant.

Bovine skin collagen is recognized internationally to be free of BSE infectivity, even if sourced from a clinically infected animal.[3] Collagen casings are used in a wide variety of food products including sausage and breakfast links, bratwurst, beef sticks, hor d'oeuvre size hotdogs, kosher hotdogs, and some high-end hams.

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[1] While bone and certain other tissues also contain collagen, skin collagen is stronger than bone collagen and therefore a far superior starting material for casings. We are not aware of any manufacturer of collagen casings in the world that uses bone collagen. Most collagen casings are made from bovine skin collagen, although some casings are made from porcine skin collagen.

[2] The only possible exposure of the hide to SRMs would result from brain splatter during stunning, which occurs prior to slaughter and hide removal. However, any brain material adhering to the hide would be minimal and would be present only on the outer layer of the hide. Such brain matter likely would be removed from the hide in the cooling water or during subsequent washing and de-hairing of the hide at the tannery. In addition, any brain matter likely would be present only on the face plate, which is removed from the rest of the hide prior to fleshing. Finally, any brain matter would only be present on the outer layer of the hide, and that outer layer is stripped away and used for leather production; only the corium, the inner layer of the hide, is used in the production of collagen casing.

[3] The Office International des Epizooties (OIE) recommends no BSE-related restrictions on trade in collagen from hides and skins, regardless of the BSE status of the country of origin. 69 Fed. Reg. at 42295; OIE, *Terrestial Animal Health Code 2003*, Article 2.3.13.8.

2. In the case of bovine skin collagen, and products made from bovine skin collagen, the proposed recordkeeping requirements should be satisfied by records showing that all collagen is made from cattle hides obtained from federally inspected establishments.

Under the proposed rule, Devro would be required to retain records demonstrating that its products are not manufactured from, processed with, or otherwise contain "prohibited cattle materials." Under FDA's interim final rule, the term "prohibited cattle materials" includes any material from non-ambulatory disabled cattle as well as any material from cattle that have not been inspected and passed. 69 Fed. Reg. 42256, 42273 (July 14, 2004)(21 C.F.R. § 189.5(a)(1)).

Devro and its customers should only be required to maintain records showing that our collagen casings are derived from hides obtained exclusively from federally inspected establishments. Such records should be sufficient to document that our collagen casings contain no prohibited cattle materials. Since USDA Food Safety and Inspection Service (FSIS) regulations prohibit the slaughter of non-ambulatory disabled cattle,[4] such records demonstrate that our collagen casings are not made from material from non-ambulatory disabled cattle. Since all cattle slaughtered at federally inspected establishments must pass ante-mortem inspection, such records demonstrate that our collagen casings are not made from cattle that have not been inspected and passed.

3. A continuing guarantee should satisfy the recordkeeping requirement.

Devro purchases collagen from tanneries that obtain cattle hides exclusively from federally inspected establishments. As previously noted, no non-ambulatory cattle may be slaughtered at a federally inspected establishment, and no cattle may be slaughtered at a federally inspected establishment unless it first passes inspection. Under these circumstances, we believe the only relevant record is an affirmation by the tannery that all of its hides come from federally inspected establishments.

Devro, should be able to satisfy its recordkeeping requirements by maintaining such an affirmation from each of the tanneries that supplies it with collagen. Moreover, a continuing guarantee by the tannery that all of its hides are obtained exclusively from federally inspected establishments should be sufficient. Such a Letter of Guarantee should include contact information and should be renewed annually. Devro, in turn, would pass a copy of this Letter of Guarantee on to its customers.

A requirement that documentation be obtained for each shipment of collagen would be difficult to comply with and unnecessary. A tannery typically obtains hides from more

[4] 69 Fed. Reg. 1862, 1873 (Jan. 12, 2004) (9 C.F.R. §§ 309.2(b), 309.3).

than one slaughter establishment, and the hides, and the collagen derived from the hides, are pooled. It would be extremely difficult for the tannery to identify a particular shipment of collagen with a particular shipment of hides, and maintaining the identity of hides and collagen throughout the production chain would be even more difficult. If all of the collagen comes from hides obtained from federally inspected establishments, such lot-by-lot records are unnecessary.

Similarly, importers should be able to satisfy the recordkeeping requirement by means of a continuing guarantee. In the case of imported bovine skin collagen and collagen casings, a continuing guarantee demonstrating that all collagen used was obtained from the hides of cattle slaughtered at establishments that meet FSIS equivalency standards should be sufficient.

5. FDA should allow more than 30 days for industry to comply with a final rule.

FDA is proposing that its final recordkeeping rule would become effective 30 days after publication in the *Federal Register*. Thirty days is not enough time for industry to bring its records and recordkeeping practices into compliance. Devro requests that industry be given at least 90 days to comply with any new recordkeeping requirements.

6. FDA has seriously underestimated the economic impact of the proposed rule.

In its preliminary regulatory impact analysis, FDA appears to have omitted entire industries that would be subject to the proposed rule. FDA's analysis seems only to consider the industries that are end-users of cattle materials and to overlook industries that produce intermediate products. As a result, it includes no mention of the proposed rule's impact on manufacturers of collagen casing, gelatin, and other intermediate products. We hope that FDA will correct this oversight in the final rule.

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In conclusion, Devro urges FDA to revise the proposed rule to provide that a manufacturer of collagen casing may satisfy its recordkeeping responsibilities by retaining a continuing Letter of Guarantee, renewed annually, from each of its tannery suppliers affirming that its collagen comes exclusively from the hides of cattle slaughtered at federally inspected establishments.

We appreciate this opportunity to share our views with the agency.

Respectfully submitted,

George Hayes
Regulatory Affairs Manager
Devro Inc.

cc: Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: Ms. Fumie Yokota, Desk Officer for FDA